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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,650	10/06/2003	Regine Hakenbeck	099380.B270037	7623

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,650	HAKENBECK, REGINE	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-12,14-17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) *15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-12,14 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2008 has been entered. Claims 1-5, 8-11 have been amended. Claims 7, 13, and 18 have been cancelled. Claims 19-21 have been added. Claims 1-6, 8-12, 14-17 and 19-21 are pending. Claims 15-17 are withdrawn from consideration as being drawn to a non-elected invention. Applicant's amendments necessitate the new ground(s) of rejections presented in this office action. Accordingly, the rejections of the prior Office action are withdrawn in lieu of the rejections below.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowson et al (citation made of record in prior Office action) in view of Kell et al (citation made of record in prior Office action). Regarding claim 1, Dowson et al. disclose a

method for identifying penicillin-sensitive or penicillin-resistance streptococci previously not known to have antibiotic resistance comprising: isolating bacterial DNA and hybridizing the DNA with at least one sensitivity-specific DNA probe (Pn12) and at least one resistance-specific DNA probe (Pn11 and Pn13) (page 5859, right column second full paragraph) that specifically hybridizes to a DNA sequence specific to a penicillin binding protein gene (PBP2B) of penicillin sensitive strains of *Streptococcus pneumoniae* (page 5859, right column second full paragraph) and determining whether or not the streptococci strain is sensitive to penicillin or not by detecting which probe or probes hybridize (see page 5859 and Table 1, which recite Streptococci and strains wherein antibiotic resistance has not be determined (ND)) or wherein view little to high levels of resistance or sensitivity to penicillin has been determined).

Regarding Claim 6, Dowson et al. disclose the method wherein the probes are labeled radioactively (page 5859, right column, lines 4-6). Therefore, Dawson meets the limitations of the claims recited above.

Dowson et al do not expressly teach wherein the screening assay includes DNA from *S. pneumoniae* having unknown resistance to penicillin. However, Dowson provides sufficient evidence to the ordinary artisan to screen and/or test any streptococci strain having unknown resistance to penicillin using the claimed method steps. Dowson provides sufficient motivation for performing a screening assay as claimed using probes which specifically hybridizes to sequences specific to penicillin binding protein genes. Dowson et al teach in the introduction that the emergence of resistance to penicillin in a number of bacterial species has occurred by the

development of altered high molecular weight penicillin-binding proteins that have reduced affinity for the antibiotic (page 5858). Dowson et al identifies regions in two of the PBP2B genes of penicillin resistant pneumococci that have been found to be altered in all penicillin resistance pneumococci and teaches wherein probes are designed to target this region in order to determine antibiotic resistance in Streptococci bacterial strains (page 5859).

Kell et al supports the teaching of Dowson et al. Kell et al teach that "penicillin resistance in Streptococcus pneumonia (the pneumonococcus) is entirely due to the development of altered forms of penicillin-binding proteins (PBPs) that have decreased affinity for beta-lactam antibodies". Kell et al teach that "the PBP genes of penicillin resistance pneumococci have a mosaic structure, consisting of regions that are very similar to the corresponding regions in the genes from penicillin-susceptible pneumococci and regions that differ by as much as 20% in nucleotide sequences (see page 4382). Kell et al also teaches hybridization method steps using probe(s) targeted to sequences specific for PBP genes in order to fingerprint penicillin resistant pneumococci (see abstract 4383 and 4384).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention that the claimed invention of Dowson et al in view of Kell et al could be modified to screen any pneumococci sample having unknown penicillin resistance with a reasonable expectation of success. It would have obvious to a person of ordinary skill in the art to try to screen various DNA samples having no known penicillin resistance using the method of Dowson in view of Kell et al in an attempt to

provide alternative means of screening for new or different strains of antibiotic resistant pneumococci for epidemiological studies as taught by both Dowson et al and Kell et al.

4. Claims 2-3, 11, 12, 14, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowson et al (citation made of record in prior Office action) in view of Kell et al (citation made of record in prior Office action) and further in view of *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995).

Regarding claims 2-3, 11, 12, 19 and 21, Dowson et al. teach a method for identifying penicillin resistance in bacteria comprising: isolating bacterial DNA and hybridizing the DNA with at least one sensitivity-specific and at least one resistance-specific probe (page 5859, right column, and second full paragraph). Additionally, they teach that the PBP genes in penicillin sensitive and resistant strains of *S. pneumoniae* comprise highly conserved regions alternating with highly divergent regions (Abstract). Dowson et al. do not teach the sensitivity-specific probes are selected from SEQ ID NO: 7-13 and the resistance-specific probes are selected from SEQ ID NO: 18-19 or sequences that differ from said sequences by one to four nucleotides.

Kell et al. teach the PBP2x gene sequence of penicillin-resistant pneumococci and sequences which confer antibiotic resistance to pneumococci in patients wherein said sequence comprises the sequence of SEQ ID NO: 8 (see accession number z21803 and Figure 4). Kell et al distinguishes between sequences of pneumococci that resistant and susceptible to penicillin (see page 4388).

In the court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of

Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed sequence of the instant invention simply represent a structural homolog of the nucleotide sequences taught by Kell et al derived from sequences expressly suggested by the prior art of and known in the prior art as derived from PBP2x gene of penicillin-resistant pneumococci and useful for detecting penicillin resistance in Streptococci strains, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed nucleotide sequences are *prima facie* obvious over the cited references in the absence of secondary considerations.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the PBP2x gene sequence differences between antibiotic sensitive and antibiotic resistant strains and to use probes which hybridize to those sequences in the method of Dowson et al. for identifying antibiotic resistant bacteria for the obvious benefit of identifying clinically important antibiotic-

resistant bacteria efficiently and economically using DNA hybridization and antibiotic response-specific probes.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-6, 8-12, 14, 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6713254. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d

1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In this case, both the instant claims 1-6, 8-12, 14, 19-21 and the claims 1-12 of US Patent 6713254 are directed to a method for testing Streptococcus pneumoniae for resistance to penicillin comprising isolating DNA from a streptococcus strain, hybridizing the DNA obtained in step (a) with at least one sensitivity specific PNA probe and at least one resistance-specific DNA probe and determining whether or not said Streptococcus pneumoniae strain is sensitive to penicillin or not by detecting which probe or probes hybridize. The claims instant invention only differs from the claims of US patent 6713254 in that the claims of the US patent further recites the sequences of the sensitive-specific probes in the independent claim 1. The dependent claims of the instant invention recite and define that these same sequences represent sensitive strains of *Streptococcus* pneumoniae (see for example the claims 2 of the instant invention). Thus, the claims 1-6, 8-12, 14, 19-21 of the instant invention falls entirely within the scope of the claims 1-12 of US patent 6713254. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a

terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637